SUMMARY
Background Medinor AS ordered a SKUP laboratory testing of QuickVue® In-line Strep A in September 2003 due to great interest from GP. In Scandinavia, there is no consensus on diagnosis and treatment of hemolytic streptococci.

Principle of the test. QuickVue® In-line Strep A test is an immunochromogen method. A throat swab specimen is collected and inserted into the Swab Chamber of the Test Cassette. The Extraction Solutions are mixed and added to extract the antigenic component of the bacteria. The extracted sample flows through a label pad containing rabbit polyclonal anti-strep A antibody and a blue control label. If the extracted solution contains strep A antigen, it will be seen as a pink-to-purple Test Line. A blue Control Line should always appear in a properly functioning Test Cassette. If strep A is not present or present at very low levels, only a blue Control Line will be visible. The result of the test should be read after 5 minutes at $15\text{-}30^0$ C.

Analytical quality counts 50 % of the total validation. Parameters evaluated:
1) Equivalence point. 2a) Specificity, defined by measuring other streptococci (True negative)/ (false positive + true negative). 2b) Specificity, defined from Equivalence point (True negative)/ (false positive + true negative). 3) Validation of practical use: intra-person and inter-person variation. 4) Percent of tests not valid. 5) Does the test turn positive at the time told in the insert? 6) Does the result change during time?

Practability counts 50 % of the total validation. Parameters evaluated: insert, time, possibility of quality control, operation of the test, and other factors. The results of the evaluation are indicated as follows: not relevant, not satisfactory = 0 point, less satisfactory = 1, satisfactory = 2 and very satisfactory = 3 points. Each of the 5 areas has to achieve $\geq$ 2 points.

Method
To decide the detection limits of QuickVue® In-line Strep A test we used serial dilutions of a known amount of *S. pyogenes* in seven different concentrations, one mix of four other streptococci-strains and a positive and a negative control. The extraction solution is filled into the chamber after the swab has been placed there. The result of the tests is read by 4 independent persons.

Results, *analytical quality.*
1)   *Equivalence point:* about 8.5×10^5 hemolytic streptococci/ml.
2a) *Specificity: 95.3 %. (61 of 64).*
2b) *Specificity: 96.25 % $\leq 8.5 \times 10^4$ hemolytic streptococci/ml. (308 readings of 320)*
3a) *Intra-person reading: No disagreement.*
3b) *Inter-person disagreement of reading: 1.4 % of the test (2/144).*
4)   *Invalid tests: 0.4 % (3 of 640).*
5)   *The test is positive at 5 minutes: yes.*
6)   *False positive later than 5 minutes: see text, table1 and photos.*
6b) *False negative: 0 % at a concentration of $> 8.5 \times 10^5$/ml.*

Results, *practability.* The 4 test persons could distinguish between True positives and False positives, however this can not be expected in routine. See comments.

Conclusion
QuickVue In-line® Strep A test does not fulfil the criteria for good performing in this analysis. The reason why, is the possibility of false positives due to a transitory, diffuse, red band that passes some of the test windows. The band appears within a space of 2 to 15 minutes, and the duration of the bands is about 90 seconds. Twenty-four % of the tests had to be "re-started" after 60 seconds. There is no correlation between the bands and the "re-starting" of the test. We do not expect that QuickVue In-line will perform better in less standardised conditions in the hands of General Practitioners.